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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/944,929	08/31/2001	Kevin P. Baker	P2548P1C21	2450

7590 08/12/2003

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EXAMINER
VOGEL, NANCY S

ART UNIT	PAPER NUMBER
1636	12

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,929	BAKER ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 22-41 are pending in the case. This office action is in response to applicant's amendment filed 5/16/03, Paper No. 11.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The priority date for claims 22-37 remains 1 December 1999 for reasons made of record in the previous Office action mailed 2/11/03, and for the reasons set forth below.

The rejection of claims under 35 USC 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention, has been maintained for the reasons set forth below.

New rejections are set forth below.

Response to Argument

With regard to the priority issue, applicants have argued that the claims should be given priority for the pending claims to application 09/254,311, since the '311 application discloses the polypeptide and asserts "several specific, substantial and credible utilities for the claimed invention" and "the '311 application discusses the use of the claimed invention in protein-protein binding assays, biochemical screening assay, immunoassays and cell based assays" (page 7 of the response). However, as was stated in the previous Office action, the parent application 09/254,311 did not contain an enabling disclosure. The specification of 09/254,311 teaches that PRO361 is possibly a mucin or a chitinase, however the identification of homology to a protein, without further evidence that the claimed protein or protein encoding polynucleotide possesses this activity, does not meet the standard of substantial utility, since further experimentation is necessary to attribute a utility to the claimed protein.

Claims 22-26, and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons set forth in the previous office action at pages 8 line 11 – page 10 line 10.

Applicants have argued that the inclusion in claims 22-26 of a functional limitation distinguishes the polypeptides belonging to the claimed genus from those excluded from the genus, and that the structural and functional characteristics are fully described in the specification as filed. However, the inclusion in the claims of a function for the claimed polypeptides does not remedy the lack of written description in the specification of a representative number of species encompassed by the claims so that one of skill in the art could envision all the polypeptides that may inhibit proliferation of stimulated T-lymphocytes. There is no discussion in the specification of common structural feature(s) of the genus encompassed by the claims that play a role in the inhibition of proliferation of T-cell lymphocytes. There is no disclosure of the amino acids in the hydrophobic core of the protein essential to proper folding. Therefore, the specification does not describe the claimed isolated polypeptides in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these isolated polypeptides at the time of filing the present application. Thus, the written description requirement has not been satisfied, and the rejection is maintained.

New Rejections

Claim Rejections - 35 USC § 101

Claims 22-41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification as filed does not disclose or provide evidence that a real world utility is associated with the claimed protein. Further experimentation is necessary to attribute a utility to the claimed nucleic acid encoding a protein. The specification teaches that the claimed DNA encodes a protein which is able to inhibit proliferation of stimulated T-lymphocytes in a MLR assay. However, the ability of a protein to stimulate lymphocyte proliferation in this assay does not support a specific and substantial utility for the claimed invention. This ability is assayed in an artificial in vitro system and the specification does not provide for what specific conditions or for which specific diseases the claimed invention would predictably function. It is not predictable in which conditions the claimed invention may function, if any.

Claims 22-41 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the invention, and 8) quantity

of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to an nucleic acid sequence having at least 80, 85, 90, 95, 99 or 100 % homology to SEQ ID NO: 82 or 83, with or without a signal peptide, or a nucleic acid that hybridizes thereto, and in some claims, containing the functional limitation that the polypeptide encoded by the nucleic acid is able to inhibit proliferation of stimulated T-lymphocytes. The state of the prior art regarding the ability of a protein to inhibit the MLR assay is unpredictable and uncertain, since it is an artificial in vitro system and does not indicate for what specific conditions and for which specific diseases the protein would be useful. While there are many conditions in which the inhibition of the immune response would be beneficial, the mere statement that a particular protein would be useful for any such condition does not constitute an enabling disclosure, since there is no guidance as to such crucial factors such as methods and quantity of administration. Other than the MLR assay, there are no working examples taught in the specification. There is no correlation taught or well known in the art between the MLR reaction and in vivo treatment of diseases involving the immune response. There is no guidance in the specification regarding such matters as patients that would be treated with the disclosed polynucleotides, or methods of administration. The quantity of experimentation required to use the instant invention would be large.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv
August 7, 2003

TERRY MCKELVEY
PRIMARY EXAMINER